HOUSE BILL 2976 By Cooper B

AN ACT to amend Tennessee Code Annotated, Title 53 and Title 63, Chapter 10, relative to marketing practices for pharmaceutical products.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 10, Part 5, is amended by adding the following as a new section:

63-10-511.

(a)

- (1) Annually on or before January 1 of each year, every pharmaceutical manufacturing company shall disclose to the board of pharmacy the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the manufacturer, directly or through its pharmaceutical marketers to any physician authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the board. Initial disclosure shall be made on or before January 1, 2008, for the twelve (12) month period ending June 30, 2007. The board shall provide to the office of the attorney general and reporter complete access to the information required to be disclosed under this section. The office of the attorney general and reporter shall report annually on the disclosures made under this section to the general assembly and the governor on or before March 1.
- (2) Each company subject to the provisions of this section shall also disclose to the board, on or before October 1, 2006, and annually thereafter, the

name and address of the individual responsible for the manufacturer's compliance with the provisions of this section.

- (3) The board and the office of the attorney general and reporter shall keep confidential all trade secret information, as defined by Section 47-25-1702. The disclosure form prescribed by the board shall permit the company to identify any information that is a trade secret.
 - (4) The following shall be exempt from disclosure:
 - (A) Free samples of prescription drugs intended to be distributed to patients;
 - (B) The payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials; provided, however, as used in this subdivision, "clinical trial" means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies or new ways of using known treatments;
 - (C) Any gift, fee, payment, subsidy or other economic benefit the value of which is less than thirty dollars (\$30.00); and
 - (D) Scholarship or other support for medical students, residents and fellows to attend a significant educational, scientific or policy making conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.
- (b) The attorney general and reporter may bring an action in the chancery court of Davidson County for injunctive relief, costs, and attorneys' fees, and to impose on a pharmaceutical manufacturing company that fails to disclose as required by subsection

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- (a) of this section a civil penalty of no more than ten thousand dollars (\$10,000) per violation. Each unlawful failure to disclose shall constitute a separate violation.
 - (c) As used in this section:
 - (1) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a manufacturer, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.
 - (2) "Pharmaceutical manufacturing company" or "manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale drug distributor or a pharmacist licensed under title 63, chapter 10.

SECTION 2. This act shall take effect July 1, 2006, the public welfare requiring it.

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